PHARMALEX

CONFIDENCE BEYOND COMPLIANCE

THE END-TO-END SOLUTION FOR SPECIALIZED PHARMA AND BIOTECH

DISCOVERY / NON-CLINICAL | CLINICAL DEVELOPMENT | MARKET AUTHORIZATION / APPROVAL | PRODUCT MAINTENANCE

Today's ever-changing regulatory environment requires expertise and innovative solutions to overcome the current and future challenges that companies face. Based on the feedback of more than 600 clients we have tailored our unrivaled services to address your needs regardless of company size. Our portfolio bundles all of our extensive development consulting, regulatory, quality management and pharmacovigilance expertise together to support you in bringing your new drug or device to market, as well as maximizing its value through lifecycle developments.

PharmaLex helps companies to:

1 Accelerate your product's **time-to-market**.	**2** Drive successful product development, with our **one-stop solution**.	**3** Utilize our **extensive local network** of health agency connections.	**4** Reduce risk by engaging our range of **subject matter experts**.	**5** Navigate through the regulatory process, **mitigating the risks**.

The services within this bundle include anything from scientific advice (FDA/EMA), orphan drug designation, ATMPs support and biosimilar development.

1. TIME-TO-MARKET

We offer increased productivity, reducing time-to-market or even getting there first.

"We were 6 months behind our competitor for MA when we hired PharmaLex; they integrated into our team to close the gap resulting in approval 6 months ahead – a total gain of 12 months!"

VP, Biotechnology Company

SAVED 2-3 YEARS
BY AGREEING AN ACCELERATED DEVELOPMENT PATHWAY WITH HEALTH AUTHORITIES FOR SPECIALIZED PHARMA COMPANY.

SUCCESSFULLY CONDUCTED SEVERAL
'FIRST-IN-CLASS'
SWITCHES TO OTC FOR DIFFERENT PHARMA COMPANIES.

2. ONE-STOP SOLUTION

This model relies on the successful partnership with your PharmaLex account manager, someone who is on hand when you need them, operates in your time zone, and who provides the innovative solution you need.

"PharmaLex advised, built and managed our lead investigational molecule. They helped us globalize the molecule from the ground up and take it international, to both US and European markets."

Head of Scientific Affairs, Biotechnology Company

DELIVERED INTERNATIONAL PRODUCT ROLL-OUT ACROSS MULTIPLE COUNTRIES FOR INDEPENDENT PHARMA COMPANY WITH SINGLE POINT OF CONTACT.
RESPONSIVE WITHIN 24H.

COORDINATED ALL REQUIRED DRUG DEVELOPMENT SERVICES (INCLUDING DRUG SAFETY) AS
SOLE PROVIDER
FOR A BIOTECHNOLOGY COMPANY.

3. EXTENSIVE HEALTH AUTHORITY NETWORK

Our team including former employees of regulatory authorities offers in depth insights and knowledge of health agencies' current thinking-first-hand know-how of the health agencies.

"We recently had some tricky FDA meetings and the PharmaLex team was at hand to guide us through the process. They acted as an extension of our team and because they anticipated the needs, were pro-active to advise us on the best path forward before we were in a serious situation. It's been so important to tap into that insider knowledge to put us one step ahead of the curve."

Specialist, Pharmaceutical Company

LEAD 40+
HEALTH AGENCY INTERACTIONS ANNUALLY WITH EMA/FDA.

25+ YEARS
OF EXPERIENCE IN PRE-AUTHORIZATION SUBMISSIONS, INCLUDING REGULAR INTERACTIONS WITH FDA, EMA AND ALL OTHER RELEVANT REGULATORY HEALTH AGENCIES.

WORKED WITH A
RANGE OF BODIES
ACROSS THE EMA (CAT, PDCO, COMP); PMDA (JAPAN) AND FDA (CDER, CBER, SFDA).

4. SUBJECT MATTER EXPERTS

Our extensive and highly qualified team of subject matter experts, deal with regulatory agencies worldwide; we helped bring one of the first ATMPs to market. Our expert knowledge includes New Chemical and Biological Entities (NCEs, NBEs), Biosimilars, Generics and Value Added Medicines.

"Our cell-derived product received a marketing license thanks in a large part to PharmaLex. Their specific knowledge and experience in this innovative field was critical in helping us to navigate through both the complex discussions and document preparation needed for meetings with the regulatory authorities as well as licensing applications."

Medical Director, Biotechnology Company

OVER 1000
EXPERTS WORKING IN COUNTRIES ACROSS THE GLOBE.

WE HOST NUMEROUS INTERNATIONAL FACE-TO-FACE AND VIRTUAL
LECTURES
LED BY OUR SUBJECT MATTER EXPERTS.

5. MITIGATE RISK

To navigate through the complexities of development activities we provide guidance and strategic insights to determine the optimal path right from the start.

"The PharmaLex team stepped in at a critical time when we were applying for a new chemical entity status for an established product. Their quick thinking and forward-looking approach flagged a missing protection document which saved us thousands of Euros and of course time we didn't have!"

Head of Product Development, Biotechnology Company

75%
OF PROJECTS PASSED SUCCESSFULLY THROUGH DEVELOPMENT PHASE
WITHOUT MAJOR FINDINGS.

➤ PHARMALEX contact@pharmalex.com www.pharmalex.com

Service Overview

PharmaLex can support clients throughout the product lifecycle. Here we provide a non-exhaustive selection of our modular service portfolio. Please contact us to identify a customized solution for your company's specific needs.

DISCOVERY / NON-CLINICAL → CLINICAL DEVELOPMENT → APPROVAL / AUTHORIZATION

Integrated Program & Project Management: coordination of development projects & submissions, product development plan regeneration.

CMC Development: product characterization, support of formulation & analytical method development, process validation, QBD, continued process verification & accelerated development strategies, definition of critical quality attributes & specifications, release & stability testing strategies.

Regulatory Strategy & Development Services: health authority meetings, gap analyses of regulatory & scientific documents, assessment of special designation opportunities, due diligence evaluations.

Non-clinical Development Services: program design / protocol development & review, vendor selection & oversight.

Clinical Development Services: clinical development plan, study design/protocol development & review, CRO selection and oversight, study management, CSR writing.

Biostatistics & Data Management Services: CMC/QBD, non-clinical & clinical studies: e.g. SAPs, meta-analyses, ISS/ISE support, PK/PD modeling, CDISC compliance, focus expertise in adaptive & Bayesian designs.

Pharmacovigilance Services: clinical study safety surveillance, SAE reporting, individual case report processing & follow up, authoring of risk management plans (USA/EU), provision of PV system including QPPV, DSUR report preparation.

Regulatory & Medical Writing: pediatric development plans, orphan designation applications, briefing books for health authority interactions, applications for special consideration (e.g. PRIME, adaptive pathways) Investigator brochures, non-clinical overviews & summaries, environmental risk assessments.

Quality Assurance & Compliance Services: QMS development & maintenance, GXP vendor qualification, GXP audits, inspection support & remediation, pre-approval inspection readiness (PAI).

Regulatory Operations: technical dossier compilation, publishing & validation, eCTD consultancy & electronic submissions; document templates & document formatting support.

Procedure Management: filling of registration documentation, procedural advice & management for US, EU and growth markets, liaison with regulatory agencies globally, delivery of local and global intelligence.

Labeling: Company Core Data Sheet and US & EU regional product information creation.

Market Access Services

Customer On-site Support: a convenient, tailor-made and cost effective solution for companies looking for short-, medium- and long-term resource.

CONTACT US